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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,741	02/18/2000	Victor S Lobanov	1503.0730000	7797

7590 09/26/2002

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EXAMINER
MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/26/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/506,741	Applicant(s) LOBANOV ET AL.	
	Examiner Ardin Marschel	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 July 2001 and 03 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *4-6 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-27 and 31-48* is/are rejected.

7)☒ Claim(s) *1-3,7-21,25-27 and 31-45* is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *(58 sheets)*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' election without traverse of Specie D (claims 1-3, 7-27, and 31-48) in Paper No. 6, filed 7/23/01, is acknowledged.

NON-STATUTORY SUBJECT MATTER:

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 7-27, and 31-48 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The manipulation of a virtual library with compound selection is non-statutory subject matter as not being a physical or tangible process, but rather an algorithm or manipulation of abstract material.

VAGUE AND INDEFINITE UNDER 35 U.S.C. §112, SECOND PARAGRAPH:

Claims 1-3, 7-27, and 31-48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step d., the deconvoluting of compounds into reagents is set forth. This step lacks clarity as to what deconvoluting is meant. In the specification on page 20, lines 24-27, deconvoluting is described as deconvoluting M compounds into their building blocks. The lack of specificity of wording in claim 1, step d., causes the interpretation of the deconvoluting in claim 1 to be broader and therefore non-commensurate in scope with the specification. It is vague and indefinite as to whether the claim step should be interpreted exactly as worded in the specification on said page

20 or whether the metes and bounds of this step in claim 1 are broader and therefore undefined. For example, are "all" reagents" that would be utilized as building blocks required in said step d? or some subset thereof. Is the deconvoluting of said step d., satisfied by listing the functional component moieties of the M compounds? Clarification via clearer claim wording is requested. The above unclarities are also in the other independent claims under examinination as well as claims dependent from either claim 1 or said other independent claims via their dependence.

In claim 1, lines 1 and 2, the method is directed to the selection of one or more compounds from a virtual library. Confusingly, the steps of the method proceed to ending with enumerating a plurality of reagents. It is noted that these reagents are enumerated to produce a second set of compounds, but this enumerating step does not actually produce these compounds but is only an enumerating step. It is also confusingly noted that reagents are enumerated and not compounds as the M compounds in step d. It is unclear what compound selection is meant in order to accomplish the method as set forth in lines 1 and 2 of claim 1. Is step c. of claim 1 the actual accomplishment of the selection method of claim 1? If so, what is meant by steps d. – f.? Clarification via clearer claim wording is requested. The above unclarities are also in the other independent claims under examinination as well as claims dependent from either claim 1 or said other independent claims via their dependence.

Also, in claim 1, line 1, the method is indicated as being directed to "selecting one or more compounds". This is reasonably interpreted as indicating that the result of the selection process includes one compound being selected, or, alternatively, a

plurality of compounds being selected. At the end of claim 1 a second set of S compounds (plural) is produced. This set S seems to be described thereby as containing a plurality of compounds which possibly (See above unclarities.) is the result of the instant claim 1 method. The word "compounds" is plural and seems to exclude the option of set S containing only one compound. Thus, it is confusing as to what is meant by line 1 of claim 1 including a "one compound" selection option whereas the last two lines of claim 1 seems to require, and be limited to, a plurality of compounds. Which phrase controls the metes and bounds of claim 1? Is the method directed to one or more compounds selection or is the method limited to a plurality of compounds selection? Clarification via clearer claim wording is requested. The above unclarities are also in the other independent claims under examinination as well as claims dependent from either claim 1 or said other independent claims via their dependence.

In claims 1-3, 7-23, 25-27, and 31-47, the claims are unclear as to whether the steps therein are only performed as virtual or computer steps or may alternatively be performed with physical chemical processes. Clarification via clearer claim wording is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1–3, 7-27, and 31-48 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Lobanov et al.[J. Chem. Inf. Comput. Sci. 40:460(2000)].

The reference is noted at the bottom of page 460 as being published on the web prior to the instant filing date. It is thus prior art to the instant application. Also, it is noted that the instant inventorship is different from the authorship of said reference thus supplying documentation of the instant invention being known or used by others. A Katz type declaration, which explains said inventorship versus said authorship difference, may overcome this rejection. It is noted that this publication, taken as a whole, discloses the instantly claimed invention.

Claims 25-27, 31-37, 47, and 48 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Tokizane et al. (P/N 4,811,217; Ref. AA1).

Tokizane et al. discloses the computerized selection of some number, N, with broadly various generic elements XX, in the reference, of ring structure compounds set forth as Structure 1 in column 4, lines 55-63, out of R possible generic compounds as summarized in column 3, lines 40-63, thus making N<R, as in step a. of instant claim 25. In column 4, lines 64-66, the compounds M are defined wherein XX can only be

one of two component, oxygen containing ring systems, with a ring size of five or six. This specific set of M compounds of this type is fewer in number (M<N) than the more generic structure 1 depicts, as in step b. of instant claim 25. This set of M compounds is then deconvoluted into component reagent parts as summarized as the elements 1-8 in TABLE 1 in columns 5-6 as in step c. of instant claim 25. A search is then conducted utilizing a query structure as, for example, structure 2 at the bottom of column 6 to produce a focused set or library of matches. A search process is disclosed starting in column 8, line 33, and extending through to column 11, line 15, wherein in column 11, lines 11-12, the result being inclusive of one or more matches is set forth as the selected compounds, set S, as instantly claimed in claim 25, step d. The column 11 citation includes both multiple or duplicate matches as well as exact matches "in every respect" as in lines 11-15, thus including the K<S selection of exactly matching compounds in instant claim 26. The reagents are as listed in the element table as required for predetermination of what reagents are required for the production of K compounds in instant claims 27 and 33. The fitness function selection of instant claims 31, 32, and 34-37 is deemed to be met by the required ring structures as being fit for element definitions as utilizable in the method of the reference.

Claims 1-3, 7-23, 25-27, and 31-47 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Eaton et al. (P/N 5,789,160; Ref. AG4).

This rejection utilizes the disclosures of Eaton et al. which are available due to the above noted unclarity as to whether the actual claim steps may or may not be performed within a computer system due to unclarity of claim wording as noted above.

In Figure 1 of Eaton et al. N reagents combinations are depicted as nucleic acid sequences; specifically A, B, and C; which are separately attached to reagents depicted by geometric shapes, triangle, hexagon, etc. These are specific reagent combinations, N, selected from the random nucleic acids, of reagents options. Clearly, a specific number, N, is less than R nucleic acids in a random set of such reagents, as required in step a. of instant claim 1. These reagent combinations are enumerated as NA(sequence-A) attached to R/triangle etc. at the bottom of the first down arrow of said Figure 1 and also required in step b. of instant claim 1. The partitioning and amplification steps select M compounds, ranked as acceptable, as required in step c. of instant claim 1 and via fitness as in instant claims 7, 10-15, 21, and 22. The molecular descriptors are moieties which permit the partitioning and amplification in this step and also required in instant claims 16-20. The Large scale synthesis step deconvolutes the M compounds into component reagents for synthesis. The focused library is the R/triangle compound as also required in step e. of instant claim 1. The desireable product is thus enumerated as a second set, S, as required in claim 1, step g. Thus, claim 1 is anticipated by the reference. This is also summarized in the Parallel SELEX process in columns 5-6 of the reference in the section, entitled, "BRIEF SUMMARY OF THE INVENTION" as well as reiterated in detail in the "DETAILED DESCRIPTION OF THE INVENTION" starting in column 7. The product library can be further subjected to a fitness function selection as well as a predetermined reagent selection as summarized in the reference in column 5, lines 52-65, and also required in instant claims 2, 3, 8,

and 9. The methods of instant claims 25 etc. are similarly anticipated due to these claims being broader and not limited to reagent combinations in various steps therein.

Claims 1-3, 7-27, and 31-48 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Young et al.(EP 0,818,744; Ref. AO1).

Pages 1 and 2 of the reference summarize a process of drug compound selection which includes computerized modeling, identification of fragments which fit into a binding site, generating a list of reagent compounds which make up a set of ranked by fitness and selected compounds, followed by various second and third and more virtual library selections corresponding to sets, K and S, of the instant claims. The specifics of this method are more detailed in that the initial reagent sets N, R, M, and F of the instant claims are described as various levels of subset selections of initial candidate compounds. These various levels are directed to selecting regarding atom content, commercial availability, expense of procurement, effectiveness, etc. as summarized on page 6, lines 1-31, of the reference. This computational method anticipates the above listed instant claims.

The cited reference AO2, WO 95/01606, is noted as not being applied due to being cumulative to the system as applied above in the reference by Tokizane et al.(Ref. AA1).

The cited reference AK4; U.S. Patent No. 5,858,660; is noted as not being applied due to being cumulative to the method as applied above in the reference AG4, U.S. Patent No. 5,789,160.

The references by Graybill et al.(P/N 6,127,191); Cramer et al.(P/N 6,240,374); and Griffey et al.(P/N 6,253,168) are all cited as of interest on the enclosed PTO Form 892 due to each describing combinatorial syntheses including reagent combination selections based on fitness determinations.

IDS considerations:

On the 1449, filed 5/2/01, the citation to the International Search Report as well as some other citations are lined through because there is no date of publication for each of them. The issuance date of said International Search Report is not a date of publication.

OBJECTIONS:

The disclosure is objected to because of the following informalities:

It is noted that capital letters are utilized as Figure designations, such as for Figure 9A, 9B, etc. In the specification on pages 5 and 6 the apparently corresponding Brief Description utilize small letters. The removal of these conflicting designation differences is required. It is suggested to amend the specification designations to be consistent with those in the Figures. It is additionally noted that conflicting designations are set forth in the specification, for example, at page 36, line 26, etc.

Appropriate correction is required.

Claims 1-3, 7-21, 25-27, and 31-45 are objected to because of the following informalities: Periods within claims are improper, except in abbreviations. Applicants are required to replace the various periods in subpart designations, such as the period

in "a." of claim 1, line 3, with non-period containing designations, such as, for example, "a)" or "(a)". Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 23, 2002

ARDIN H. MARSCHEL
PRIMARY EXAMINER